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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,451	04/09/2004	Timothy G. Laske	P-8555.00	1348

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EXAMINER	
PATEL, JOY	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,451	LASKE ET AL.	
	Examiner	Art Unit	
	Joy P. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 9, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-6* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On paragraph 16, line 7, "...either automatically of..." should be changed to "...either automatically or..."

Appropriate correction is required.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 3 (the second one), 4, and 5 have been renumbered as 4, 5, and 6 respectively.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (US 2004/0002743).

4. In regard to claim 1, Park discloses, "Atrial sensing circuits 82 and ventricular sensing circuits 84 may also be selectively coupled to the right atrial lead 20, coronary sinus lead 24,and the right ventricular lead 30...for detecting the presence of cardiac activity in each of the four chambers of the heart" (Paragraph 36, lines 1-5). Park further discloses, "The outputs of the atrial and ventricular sensing circuits, 82 and 84, are connected to the microcontroller 60, which in turn, are able to trigger or inhibit the atrial and ventricular pulse generators, 70 and 72, respectively, in a demand fashion in response to the absence or presence of cardiac activity in the appropriate chambers of the heart" (Paragraph 37, lines 9-14); See also paragraph 38. Therefore, certain parameters are being sensed by the sense amplifier, which processes these signals to determine if there is an arrhythmia. If there is an arrhythmia, it activates a pulse generator to provide therapy to the heart until the sense amplifiers receive data indicating that the arrhythmia has ceased. Therefore, the "effectiveness of the selected parameter" can be the physiological parameter sensed to determine if an arrhythmia is present. If it is present, the "effectiveness" is adjusted until the arrhythmia terminates. This parameter can be one of "a predefined rate zone limit (i.e., bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones) and various other characteristics (e.g., sudden onset, stability, physiologic sensors, and morphology, etc.)" (Paragraph 38, lines 12-15).

5. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Kroll (EP 1,084,730).

6. In regard to claim 4, Kroll discloses, "An implantable cardioversion device includes a sensor for sensing intrinsic cardiac activity in a cardiac chamber...and filtering the same using a bandpass filter having an adjustable center frequency" (Abstract, lines 1-5). Kroll further discloses, "In the illustrated embodiment, pacemaker 10 includes an analog section 12 and a digital section 14 incorporated in an hermetic implantable housing 16...Leads 32 and 34 connect the pacemaker 10 to the atrial and ventricular chambers of the heart 36, respectively" (Column 6, lines 7-16; paragraphs 27 and 28). Kroll further discloses, "Briefly, an implantable cardiac stimulator constructed in accordance with this invention includes a sensor for sensing intrinsic cardiac activity in the heart of a patient...Preferably the sensor includes an amplifier...and a filter for filtering the signals prior to providing the same to the detector. Importantly, the filter has a programmable or adjustable center frequency fc. A controller is also provided to control the center frequency fc of the filter" (Column 2, lines 42-47).

7. Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Fain et al. (US 6,636,764).

8. In regard to claims 5 and 6 Fain discloses, "Referring now to FIG. 1, a rate branch algorithm within which the Maximum Time to Diagnosis (MTD) algorithm may be implemented is discloses. The MTD algorithm of the invention can be

used in the context of a rate branch algorithm or could be used with other discrimination algorithms or could be used with other discrimination algorithms where identification of a possible ventricular tachycardia in the presence of a supraventricular tachycardia (SVT) is desirable and arrhythmia detection qualifiers may delay diagnosis of the rhythm. While described in the context of a dual chamber ICD, the invention can alternatively be implemented in a single chamber or other multiple chamber device" (Column 2, lines 31-42). Fain further discloses, "The morphology template that is used during the episode can either be acquired and validated by the physician, or it may be acquired automatically by the device. In the St. Jude Medical Photon DR device in which the Rate Branch algorithm is implemented, an Automatic Template Update algorithm periodically evaluates the current template to determine if it is representative of the patient's intrinsic rhythm, and if necessary, acquires a new template. This feature reacts to changes in the patient's morphology that can occur due to lead maturation or changes in the patient's medication" (Column 3, lines 44-53). Therefore the "parameter" (the template) is responsive to changes in the lead environment that can occur due to events, such as lead maturation. Since Fain discloses that the algorithm is responsive to lead maturation, it is inherent that a lead would have to be placed into the tissue. It is also known that leads must be implanted into the heart for an implantable pacemaker to actually affect the heart.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (US 2004/0002743) in view of Heil et al. (US 6,256,541).

10. In regard to claim 3, Park discloses, "The system includes a sensing circuit that generates an electrical signal representing electrical activity of the patient's heart. The system further includes a morphology detector that measures a magnitude of a T wave characteristic of each T wave in the electrical signal of a predetermined number of cardiac cycles of the heart and a discriminator that determines, responsive to the measured T wave characteristic magnitudes, if a T wave alternan pattern is present" (Paragraph 9, lines 6-12). However, Park does not teach an IMD with a sense amplifier that can be adjusted to include the desired events within a certain frequency. On the other hand, Heil discloses a cardioverter/defibrillator wherein "the cardiac morphology detector 232 includes an analog filter for filtering cardiac signal noise sensed by the electrodes" (Column 11, lines 65-67). Since noise is eliminated from a signal by applying a filter (e.g., high-pass, bandpass, low-pass) to remove the unwanted frequency

components in order to obtain a more accurate signal, it would have been obvious to one of ordinary skill in the art to modify the device of Park in view of the teachings of Heil so that accurate adjustments can be made to the pacemaker.

Allowable Subject Matter

11. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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